DIAZINON TECHNICAL BRIEFING

December 5, 2000

Overview of Day's Activities

- Legal framework and regulatory history
- Provide usage profiles
- Present risk assessments
- Questions and comments

Goals of Meeting

- Provide an understanding of EPA's risk assessments
- Answer your questions
- Identify risks of concern
- Begin risk mitigation dialog

Legal Context

FQPA amendments to FIFRA required

- Reassessment of all existing tolerances
- Aggregate assessments
- Safety factor for children
- Cumulative assessments

EPA Implementation of FQPA

- Formation of Tolerance Reassessment Advisory Committee (TRAC)
- Development of science policies
- Development of pilot process for public participation
- Focus on OPs

TRAC Pilot OP Review Process

- Phase 1 (30 days)
  - Registrant “error only” review
- Phase 2 (up to 30 days)
  - EPA considers registrants’ comments
- Phase 3 (60 days)
  - Public comment on preliminary risk assessment

TRAC Pilot OP Review Process

- Phase 4 (90 days)
  - EPA revises risk assessments, holds public meetings/technical briefings
- **Phase 5 (60 days)**
  - **EPA solicits risk management ideas**
- Phase 6 (up to 60 days)
  - EPA develops final risk management strategies

Regulatory History and Comments

Ben Chambliss, Chemical Review Manager
Special Review and Reregistration Division
OPP

Regulatory History

- First registered in 1956 by Ciba Geigy
- Registrants are:
  - Syngenta
  - Mahketshim-Agan
  - Drexel
  - Prentis
  - Gowan
  - Aventis
- Special Review 1986
  - Based on avian concerns
  - Resulting in cancellation of sod farm and golf course uses

Regulatory History

- Registration Standards issued in 1988
  - Restricted use for all outdoor uses other than home lawn & gardens
- Avian risk reduction strategy for granular pesticides 1992
  - Added additional limitation to protect birds

Phase 3 Public Comment

- Over 500 comments received
- Comments received from:
  - Registrants
  - Environmental/Consumer Organizations
  - Commodity Associations
  - Government Officials
  - Growers
  - Pest Control Operators
  - Lawn Care Professionals
  - Private Citizens

Environmental and Consumer Comments

- Human exposure
  - Especially risk to children
  - Incidents
- Avian risk
  - Incident driven
- Water concerns
  - Contamination in surface water, rain & fog

Registrant Comments

- Public perception
- Supported & non-supported uses and application methods
- Tolerance status
- Toxicological endpoint selection
- Occupational & residential exposure
- Water issues
- Error correction

User Community Comments

- Efficacy
- Affordability
- Lack of alternatives
  - Based on effectiveness & cost

Phase 4 - Revised Risk Assessments

- Changes to the risk assessment
  - Revised dietary assessment
  - Revised toxicity endpoint
  - Revised worker assessment
  - Revised residential assessment
  - Revised ecological assessment
  - Further characterization of Endangered Species concern
  - Addition of pet use exposure

Phase 5

- Technical briefing
- Revised risk assessment (incorporating all studies) available in public docket and on the internet
- Begin 60-day public participation period
- Public input on risk management
- Opportunities for growers and others to meet with EPA

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Use Profile

Neil Anderson, Agronomist
Biological and Economic Analysis Division
OPP

Use Profile

- Organophosphate Insecticide/Acaricide
- Restricted Use Pesticide for Ag. Uses due to Avian and Aquatic Organism Toxicity
- Homeowner Products Not Restricted Use
- 8 Formulations of End Use Products
  - 454 Active Labels

Use Profile

- End Use Products
  - Dust, emulsifiable concentrate, granular, liquid-ready to use, pressurized liquid, soluble concentrate/liquid, wettable powder, flowable concentrate
- Application Methods (list only representative)
  - Soil treatment (banded, in-furrow, mound, etc.), spray (low volume, high volume, surface, foliar, etc.), seed treatment, tree bark treatment, crack and crevice treatment, premise treatment, animal treatment (pour-on, spray, ear tag), etc.
- Application Equipment (list is only representative)
  - Airblast Sprayer, groundboom sprayer, aerial sprayer, chemigation, tractor-drawn granular spreader, hand-held sprayers (LP handwand, HP handwand, hose-end sprayer, etc.), aerosol can, push-type spreaders, dust box, etc.

Use Profile

- Agricultural Uses
  - Field Crops
    - Corn, hops, sugar beets
  - Vegetables
    - Onions, peppers, Brassica leafy vegetables, beans, peas, sweet corn, carrots, radish, rutabaga, spinach, Swiss chard, endive, table beets, garlic, lettuce, ginseng
  - Fruit
    - Apples, pears, prunes, nectarines, cherries, peaches, apricots, plums, blueberries, caneberries, cranberries, melons, grapes, bananas, pineapples, figs
  - Nut Trees
    - Almonds, walnuts, filberts
  - Livestock
    - non-lactating cattle and sheep

Use Profile

- Residential Uses
  - Lawn and garden – home lawn, parks, institutional turf, etc.
  - Ornamentals
  - Indoor
- Food Handling Establishments
- Other
  - USDA Quarantine Programs – fire ants, rodent burrows
  - Exterior Premise Treatments (buildings, livestock premises, etc.)

Use Profile

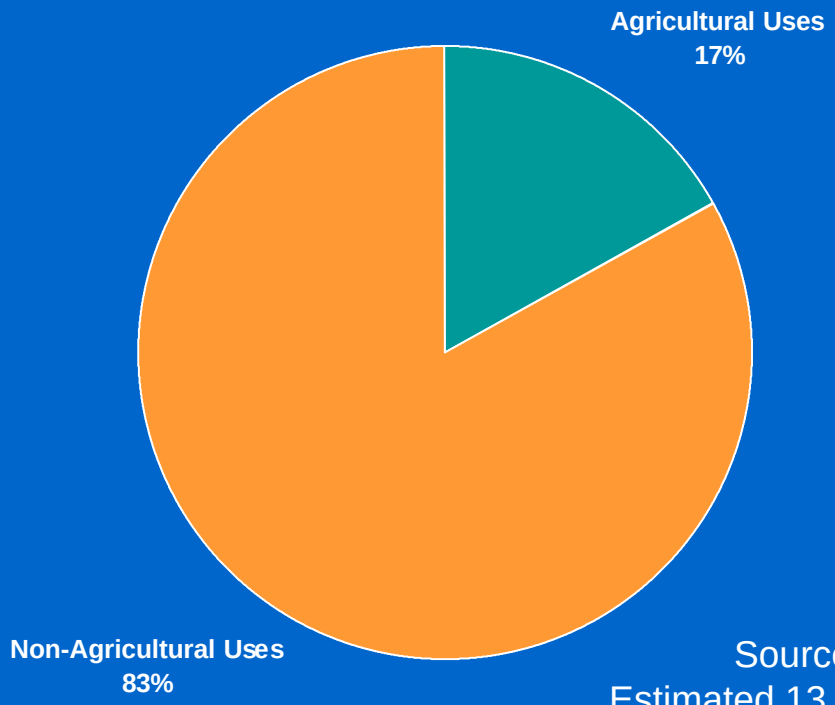
- **Average Use Rates**
  - Agricultural Uses
    - Most acreage treated between 0.5 and 2.0 lbs. ai per acre
    - Some uses with rates up to 4.0 lbs ai per acre
  - Non-Ag. Uses
    - Turf usually at 4 lbs ai per acre or less

Use Profile

- **Typical Usage**
  - Estimated 13 million lbs ai applied annually to all sites
  - Agricultural sites – 2 million lbs ai applied
    - Largest agricultural market is almonds at 12% of total lbs applied to agricultural use sites
  - Non-Agricultural sites – 11 million lbs ai applied
    - Largest non-ag. market is outdoor insect control applications by consumers at 47% of total lbs applied to non-ag. use sites
    - More than 60% of the non-ag. use is by homeowners

Use Profile

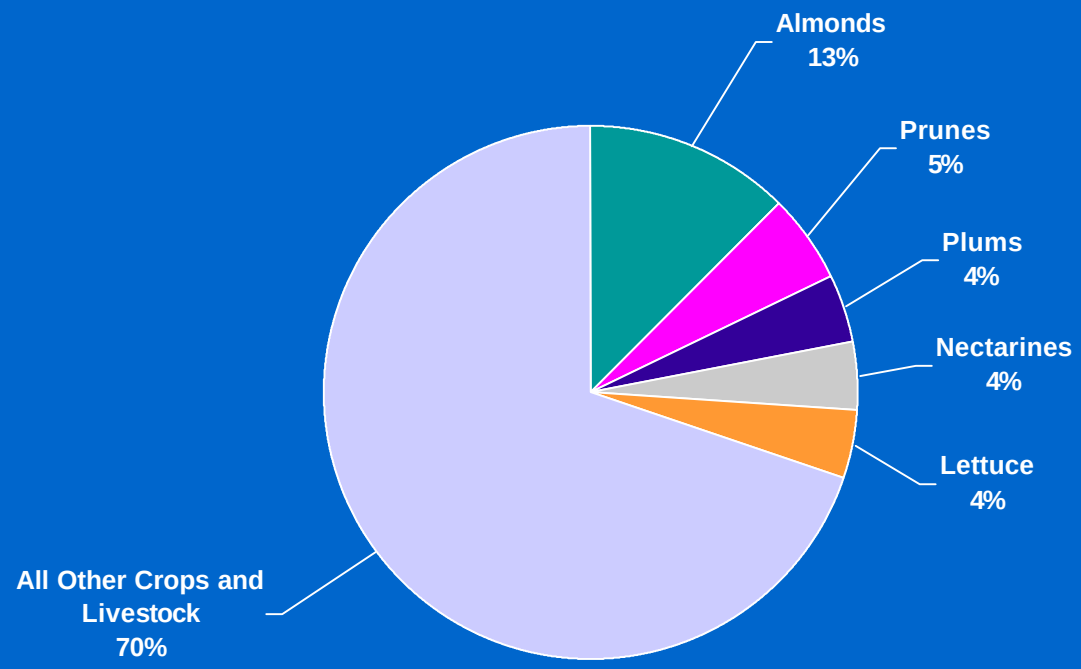
Diazinon Usage
As a % of Total lbs Applied
In Agricultural and Non-Agricultural Markets



Source: EPA Data
Estimated 13.5 million lbs applied

Use Profile – Ag. Markets

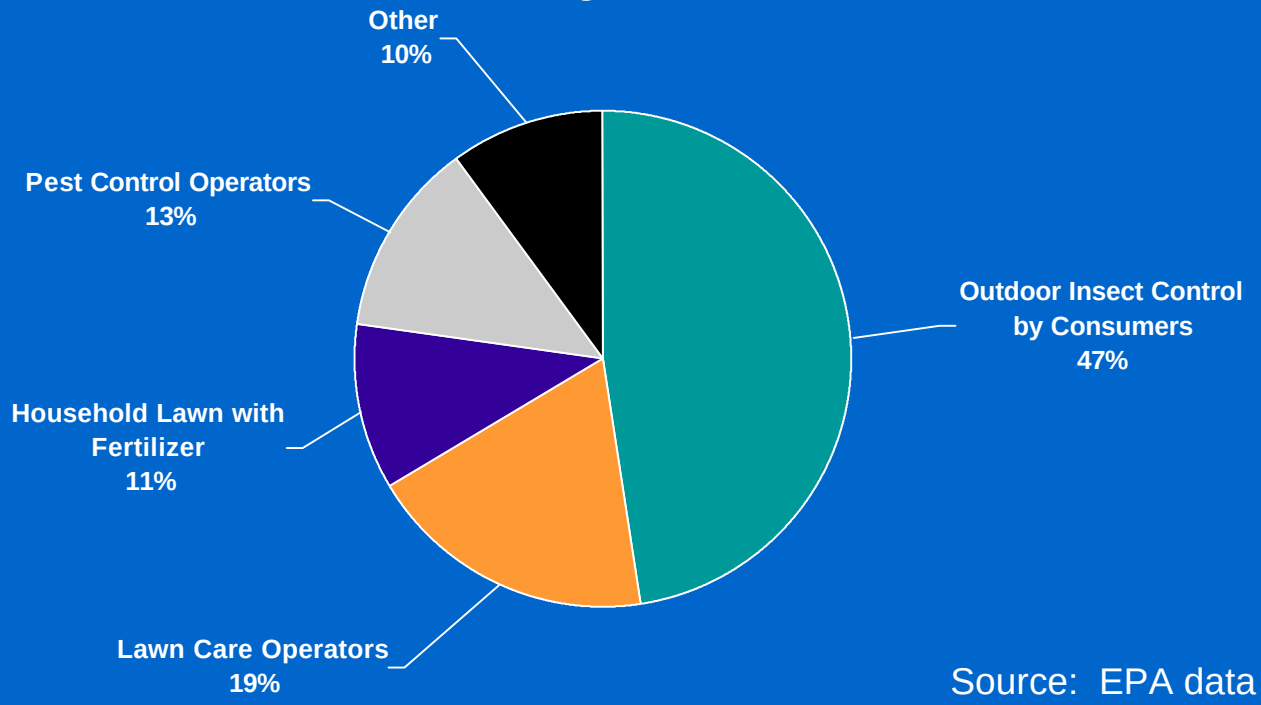
Diazinon Usage
As a % of Total lbs Applied
In US Agricultural Markets



Source: EPA Data
Estimated 2.3 million lbs Applied

Use Profile – Non-Ag. Markets

Diazinon Usage
As a % of Total lbs Applied
In US Non-Agricultural Markets



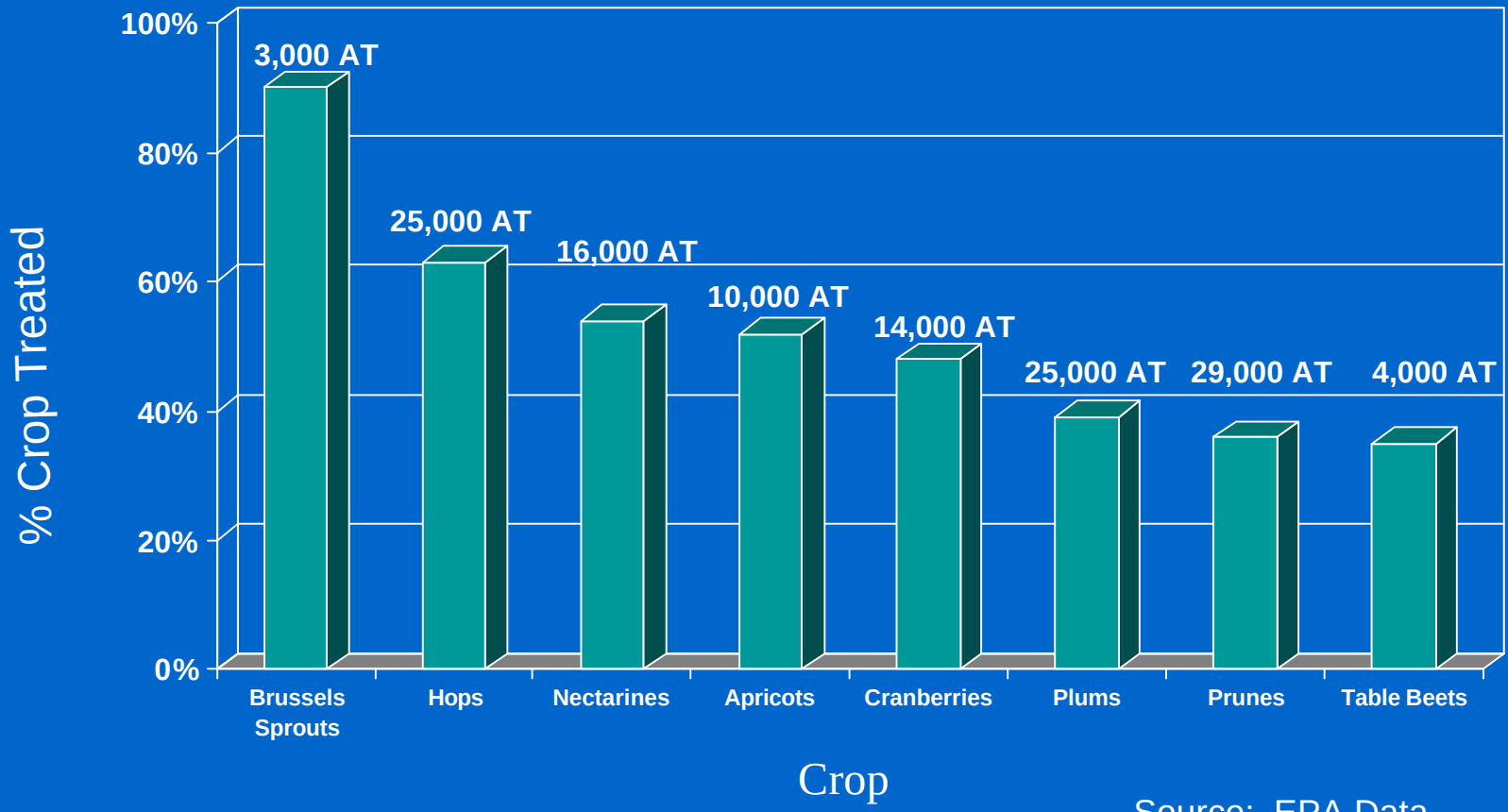
Source: EPA data
Estimated 11.2 million lbs Applied

Use Profile

- Typical Agricultural Acres Treated
  - Estimated 890,000 crop acres treated annually
    - Almond: 10% of total acres treated
    - Lettuce: 9% of total acres treated
    - No other crop accounts for >7% of total acres treated
- Major Uses by Estimated % Crop Treated
  - 8 crops with ≥35% Crop Treated (see Figure)
    - Brussels sprouts, Hops, Nectarines, Apricots, Cranberries, Plums, Prunes, Table Beets

Use Profile

Major Crop Use by % Crop Treated



Source: EPA Data
AT=Estimated Acres Treated

Use Profile

- Sources of Use Data
  - USDA/NASS
  - National Center for Food and Agricultural Policy
  - California Department of Pesticide Regulation
  - Commodity/User Groups
  - US EPA Proprietary Databases
  - Website
    - http://www.epa.gov/trac/science/

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Health Effects Risk Assessments

Danette Drew, Chemist Risk Assessor
Jess Rowland, Chief, Reregistration Branch 3
Debbie Smegal, Toxicologist/Risk Assessor
John Doherty, Toxicologist
Tim Leighton, Environmental Health Scientist

Risk Assessment Components

- Dietary
  - Food
  - Drinking Water
- Occupational (Agricultural Workers)
- Residential
  - Handlers
  - Post Application
- Aggregate
  - Food
  - Drinking Water
  - Residential

Hazard Identification Process

- Weight of evidence approach
- Review/evaluation of all toxicology studies
- Select studies appropriate for route and duration of exposure scenario
- Evaluated using current Agency cholinesterase policy

Hazard Identification Process

- Consider all adverse effects seen – species/sex/route/duration
- Select critical endpoint of concern
- Select the dose for the critical effect
- Critical toxic effect (endpoint) selected would be protective of all potential toxic effects

Effect Levels

- Lowest Observed Adverse Effect Level = LOAEL
  - The lowest dose at which an “adverse” health effect is seen (mg per kg body weight per day)
- No Observed Adverse Effect Level = NOAEL
  - The dose at which no “adverse” health effect is seen. This dose is less than the LOAEL (mg per kg body weight per day)

Uncertainty and Safety Factors

10X	Interspecies Extrapolation
10X	Intraspecies Variation
1X to 10X	FQPA Safety Factor
100X to 1000X	Total Uncertainty and Safety Factors for Risk Assessment

Acute Hazard (Toxicity)

- **Studies:** Two acute (single dose) studies
- **Endpoint**
  - Plasma cholinesterase inhibition
- **NOAEL:** 0.25 mg/kg/day
- **LOAEL:** 2.5 mg/kg/day

Endpoint reflects the potential toxicity which could result from one-day exposure to diazinon

Chronic Hazard (Toxicity)

- **Studies:** Weight of Evidence using 7 animal studies
- **Endpoint**
  - Plasma cholinesterase inhibition
- **NOAEL:** 0.02 mg/kg/day
- **LOAEL:** 0.07-0.3 mg/kg/day
  - Plasma supported by RBC cholinesterase inhibition
    - NOAEL = 0.03 mg/kg/day
    - LOAEL = 0.3 mg/kg/day
- Endpoint reflects the potential toxicity which could result from long-term exposure to diazinon

Analysis of Sensitivity/Susceptibility of the Young (FQPA Safety Factor)

- Complete toxicity database
- No developmental effects in fetuses below maternally toxic doses
- No increased sensitivity in pups relative to adults
- No abnormalities in developing fetal nervous system
- No histopathology of the nervous system
- Exposure (dietary food and water) unlikely to underestimate exposure
- Based on the above weight-of-evidence considerations, the FQPA safety factor was reduced for diazinon risk assessments

Uncertainty Factors

- 10X Interspecies Extrapolation
- 10X Interspecies Variation
- 1X FQPA Safety Factor

Total UF Applied: 100

Expression of Risk

Dietary Exposure

$$RfD = \frac{NOAEL}{UF}$$

$$PAD = \frac{RfD}{FQPA\ Safety\ Factor}$$

$$\%\ PAD = \frac{Exposure}{PAD} \times 100$$

RfD = Reference Dose
PAD = Population Adjusted Dose
(less than 100% PAD is not concern)

Population Adjusted Dose (PAD)

Acute PAD

$$RfD = \frac{0.25\ mg/kg/day}{100\ UF} = 0.0025\ mg/kg/day$$

$$aPAD = \frac{RfD}{FQPA\ SF} = \frac{0.0025\ mg/kg/day}{1} = \mathbf{0.0025\ mg/kg/day}$$

Population Adjusted Dose (PAD)

Chronic PAD

$$RfD = \frac{0.02\ mg/kg/day}{100\ UF} = 0.0002\ mg/kg/day$$

$$cPAD = \frac{RfD}{FQPA\ SF} = \frac{0.0002\ mg/kg/day}{1} = \mathbf{0.0002\ mg/kg/day}$$

Expression of Occupational/Residential Risk

$$\text{Margin of Exposure (MOE)} = \frac{\text{NOAEL}}{\text{Exposure}}$$

- The larger the calculated MOE, the lesser the concern

Occupational/Residential Risk Assessment - Dermal

- Short, intermediate, & long-term exposure
  - **Study:** 21-day dermal – rabbit
  - **Endpoint:** Plasma and brain ChE inhibition
  - **NOAEL:** 1 mg/kg/day
  - **LOAEL:** 5 mg/kg/day
  - **Target MOE:** 100 (short-term)
    300 (intermediate-term)
    300 (long-term)

Occupational/Residential Risk Assessment - Inhalation

- Short, intermediate, & long-term exposure
  - **Study:** 21-day inhalation - Rat
  - **Endpoint:** Plasma and RBC ChE inhibition
  - **LOAEL:** 0.1 μg/L (0.026 mg/kg/day)
  - **Target MOE:** 300 (all time periods)

Occupational/Residential Risk Assessment

- Target MOE: Dermal Short-term: 100
  Intermediate-term: 300
  Long-term: 300
  Inhalation (any time period): 300

Aggregate Risk Index (ARI)

- Required when different “target” MOEs exist for different routes of exposure
  - For example:
    - Target dermal MOE = 100
    - Target inhalation MOE = 300
- Individual MOEs may not be of concern (i.e., greater than target MOE)
- Aggregate exposure may be of concern

Aggregate Risk Index (ARI)

- ARI similar to MOE approach, except individual MOEs are normalized to 1 before aggregation
  - $ARI_{dermal} = \frac{MOE_{dermal\text{-}calculated}}{MOE_{dermal\text{-}target}}$
  - $ARI_{inhalation} = \frac{MOE_{inhalation\text{-}calculated}}{MOE_{inhalation\text{-}target}}$

Aggregate Risk Index (ARI)

- Aggregation using ARIs is identical to aggregation using MOEs, as follows:
  - $ARI_{aggregate} = \dfrac{1}{\dfrac{1}{ARI_1} + \dfrac{1}{ARI_2} + \dfrac{1}{ARI_3}}$
  - Where:
    - ARI_1 = Dermal ARI
    - ARI_2 = Inhalation ARI
    - ARI_3 = Oral ARI

Aggregate Risk Index (ARI)

- Generic example
  - MOE_{dermal} = 110, Target MOE_{dermal} = 100
    - Doses not exceed level of concern
  - $MOE_{inhalation}$ = 310, Target $MOE_{inhalation}$ = 300
    - Doses not exceed level of concern
- Aggregation
  - $ARI_{dermal} = \frac{110}{100} = 1.1$
  - $ARI_{inhaltion} = \frac{310}{300} = 1.03$
  - $ARI_{total} = \frac{1}{\frac{1}{1.1} + \frac{1}{1.03}} = 0.5$

less than 1, so aggregate dermal and inhalation exposure exceeds level of concern

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Dietary Risk Assessments

Danette Drew
Health Effects Division
OPP

Dietary Risk Assessments

Acute

- Reflects one-day dietary exposures to pesticide residue

Chronic

- Reflects lifetime (long-term) exposures to pesticide residues

Includes all currently registered food/feed uses

Dietary Risk Assessments

Risk = Hazard x Exposure

Dietary Exposure = Consumption x Residue

Exposure: Consumption

USDA's Continuing Survey of Food Intake by Individuals (CSFII) 1989-92 Data

- One-year surveys designed to measure what Americans eat and drink
- Represents the general population and subpopulations including infants and children

Exposure: Residue

Tier	Residue Data Used
1	Tolerance Level Residues
2	Field Trial Residues
3	Monitoring Data
	USDA PDP Data
	FDA Data

Exposure: Residue Data

Monitoring Data

- USDA's Pesticide Data Program (PDP) data
  - Prepared as in the home (e.g., washing and peeling)
  - Statistically designed for dietary risk assessment
  - Used for ~50% of commodities

Exposure: Residue Data

- Monitoring data (cont)
  - FDA Surveillance Monitoring Data
    - Designed for tolerance enforcement
    - Large number of samples and types of food
    - Used for ~35% of commodities
- Field trial data/tolerance
  - Data used in establishing EPA tolerance levels
    - Used for ~15% of commodities
- Processing Data
- Percent crop-treated data

Exposure: Residue Data

- Residues of concern
  - Diazinon
  - Hydroxy diazinon
  - Diazoxon
- Metabolites infrequently to never detected
  - Dietary assessment assumed no contribution from metabolites to the dietary exposure
  - Exceptions:
    - 1 dried fig sample (field trial)
    - 1 fresh spinach sample (PDP)

Dietary Risk

- All acute and chronic risk estimates are below level of concern
  - All risk estimates <100% PAD
  - Includes all currently registered uses
    - Even those crops being voluntarily cancelled

Probabilistic Acute Dietary Analysis Results

Phase 5 Revised Risk Assessment - Risk Estimates Percent of aPAD*

Population	99.9th Percentile Risk Estimate
U.S. Population	37
Infants <1	29
Children 1-6	63
Children 7-12	32
Females 13-50	35
Males 20+	37
Seniors	36

***aPAD = 0.0025 mg/kg/day**

Chronic Dietary Analysis Results

Phase 5 Revised Risk Assessment - Risk Estimates Percent of cPAD*

Population	Risk Estimate
U.S. Population	14
Infants <1	12
Children 1-6	22
Children 7-12	14
Females 13-50	12
Males 20+	10
Seniors	14

***cPAD = 0.0002 mg/kg/day**

Drinking Water Risk Assessment

- Lifetime health advisory level of 0.6 ppb
- Conducted because of use pattern and environmental fate profile
- Examined ground and surface water
- Drinking water assessment is based on monitoring data and modeling
- Did not include degradates
  - Parent diazinon only

Drinking Water Risk Assessment

- Groundwater
  - Modeling Data
    - SCI-GROW model based on walnut use
    - Model Estimated Environmental Concentration EEC = 0.8 ppb
    - Conservative, upperbound value

Drinking Water Risk Assessment

- Groundwater
  - Monitoring data (NAWQA, NPS)
    - More than 6000 samples (including urban and Ag shallow wells, major aquifers, domestic wells, community water systems)
    - Diazinon detected in about 2% of wells
    - EEC = 0.002 ppb (acute & chronic)

Drinking Water Risk Assessment

- Surface water
  - Modeling
    - PRZM/EXAMS models with Index Reservoir based on peach use
    - EECs = 9 ppb (chronic) and 70 ppb (acute)
    - Conservative, upperbound value

Drinking Water Risk Assessment

- Surface Water
  - Monitoring Data (NAWQA)
    - Includes more than 5000 urban & Ag streams and large streams & rivers
    - Diazinon was detected in 50% of all urban stream samples and 24% of all Ag stream samples
    - EECs = 0.5 ppb (chronic) and 3.0 ppb (acute)

Drinking Water Risk Assessment

Allowable Exposure – Food Exposure = Water Exposure

- Drinking Water Level of Comparison (DWLOC) – surrogate measure of drinking water exposure Compare DWLOC to EEC
- No concern if EECs less than DWLOC
- Potential concern if EECs greater than DWLOC

Drinking Water Risk Assessment Results

Acute EECs & DWLOCs

Population	Acute DWLOC	Acute EECs (ppb)	
		Surface (Model/Monitor)	Ground (Model/Monitor)
U.S.	56 ppb	70 ppb/3 ppb	0.8 ppb/0.002 ppb
Infants	18 ppb		
Children 1 - 6	9 ppb		

- There are no acute concerns for residues in groundwater-source drinking water
- Possible acute concern for residues in surface water-source drinking water when based on surface water modeling
  - Acute modeling EEC of 70 ppb exceeds DWLOCs for all populations

Drinking Water Risk Assessment Results

Chronic EECs & DWLOCs

Population	Chronic DWLOC	Chronic EECs	
		Surface (Model/Monitor)	Ground (Model/Monitor)
U.S.	6 ppb	9 ppb/0.5 ppb	0.8 ppb/0.002 ppb
Infants	2 ppb		
Children 1 - 6	2 ppb		

- No chronic concerns for groundwater sourced drinking water
- Possible chronic concern for residues in surface water-sourced drinking water based on surface water modeling
  - Chronic modeling EEC of 9 ppb exceeds the DWLOCs for all populations

Drinking Water Risk Assessment Uncertainties

- EECs conservative for modeling
- Drinking water (tap water) data not available
- Water treatment may form degradates
- Lawn use
  - Mitigation will result in decreased exposure

Drinking Water Risk Assessment Uncertainties

- SCI-GROW
  - Regression model based on shallow groundwater at vulnerable site (PGW study)
- PRZM/EXAMS
  - Maximum application practice
  - Default assumptions used including percent crop area factor

Monitoring Uncertainties

- Untargeted non-random site selection
- Usage, particularly in urban areas, is poorly understood
- Little data at drinking water facilities

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Occupational/Residential Exposure and Risk Assessment

Tim Leighton
Debbie Smegal
Health Effects Division
OPP

Outline of Presentation

- Agricultural Assessment - Tim Leighton
- Residential Assessment - Debbie Smegal

Agricultural Assessment

- Handlers
  - Professional pesticide applicators and farmer/growers who mix, load and apply pesticides
- Postapplication Workers
  - Workers who prune, thin, hoe, prop, scout and harvest crops following pesticide application

Residential Assessment

- Handler Exposure
  - Professionals (i.e., lawn care operators)
  - Homeowners/Residents
- Postapplication Exposure
  - Homeowners/Residents

Agricultural/Residential Risk Assessment - **Dermal**

- Short, intermediate, & long-term exposure
  - Study: 21-day dermal - rabbit
  - Endpoint: Plasma and brain ChE inhibition
  - NOAEL: 1 mg/kg/day
  - LOAEL: 5 mg/kg/day
  - Target MOE: 100 (short-term)
    300 (intermediate & long-term)

Agricultural/Residential Risk Assessment - **Inhalation**

- Short, intermediate, & long-term
  - **Study:** 21-day inhalation study
  - **LOAEL:** 0.026 mg/kg/day
    - Plasma and RBC cholinesterase inhibition
  - **Target MOE:** 300 (occupational)
    300 (residential)

Agricultural Handler Assessment

Handler Exposure and Risk Calculations

$$\text{Dose} = \frac{(\text{Unit Exposure}) \times (\text{Amount Handled})}{\text{Body Weight}}$$

$$\text{MOE} = \frac{\text{NOAEL (mg/kg/day)}}{\text{Dose (mg/kg/day)}}$$

Agricultural Handler Assessment Scenarios

Mixer/Loader	Applicator	Flagger
■ Liquids (EC) ■ WP ■ Granulars	■ Aerial ■ Groundboom ■ Airblast ■ Tractor-drawn granular spreader ■ Hand-held equipment	■ Aerial Applications

Agricultural Handler Assessment

- Data Sources
  - Labels
  - Use information
  - Standard values
  - Pesticide Handlers Exposure Database (PHED)
  - No chemical-specific studies

Agricultural Handler Risk Results

Short-term

Scenario	ARI < 1	ARI ≥ 1
32 Total (76 iterations)	71	5

Intermediate & Long-term

Scenario	MOE ≤ 10	MOE 10 - 100	MOE 100 - 300	MOE ≥ 300
32 Total (76 iterations)	21	44	7	4

Various levels of PPE or engineering controls

Summary of MOEs of Concern

MOE Range	# of Scenarios Within that Range	
	Dermal	Inhalation
<10	18	7
10 to 50	24	13
51 to 100	13	13
101 to 300	14	25
>300	6	18

Handler Assessment – Summary & Uncertainties

- Both dermal and inhalation risks are of concern
- Frequency & duration of exposure needs to be defined
  - For example number of days of application
- New toxicity data may impact short-term risks
- No chemical specific data are available

Handler Assessment – Summary & Uncertainties

- Extrapolate unit exposures to maximum application rates
- Changes to exposure factors will reduce risk
  - Inhalation rates
  - Physiologically matching body weight to surface area
- Clothing protection factors
  - Conservative estimates of 50% protection

Agricultural Postapplication Assessment

- Postapplication risk assessment based on:
  - Dislodgeable Foliar Residue (DFR):
    - Amount of pesticide residue that “comes off” a leaf’s surface when contacted by a worker
  - Transfer Coefficient (Tc):
    - Indicator of amount of foliar contact by a worker (different for each crop and activity)
  - 8 hours worked per day, adult body weight
  - Exposure duration
    - Short-term (1-7 days): Accounts for workers rotating into freshly treated fields
    - Intermediate-term (7days to several months): Accounts for long harvesting seasons
  - Toxicological Endpoint

Agricultural Postapplication Assessment

Exposure and Hazard Calculations

$$\text{Dose} = \frac{\text{DFR} \times \text{Transfer Coefficient} \times \text{Hrs Worked}}{\text{Body Weight (kg)}}$$

$$\text{MOE} = \frac{\text{NOAEL (mg/kg/day)}}{\text{Dose (mg/kg/day)}}$$

Calculated REI = Day After Treatment
When MOE $\geq$ 100 and/or 300

Agricultural Postapplication Assessment

- Sources of Information:
  - Dislodgeable Foliar Residue Data
    - Chemical and crop-specific studies (2 crops)
    - Extrapolating crop-specific studies
  - Transfer coefficients
    - Agricultural Reentry Task Force data
    - Transfer coefficient policies
  - Exposure Factors
    - Standard values (e.g., body weight, hours worked)

Agricultural Postapplication Assessment

- 13 crop groupings for postapplication exposures
  - Groupings reflect data submitted ARTF
  - High-end exposures for harvesters
  - Other harvesting activities (e.g., scouting)

Agricultural Postapplication Assessment

Crop Grouping	Days After Treatment Target MOE Achieved		PHI Days
	Short-term (target = 100)	Intermediate-term (target = 300)	
Low berry	4 to 5	6 to 7	5 to 7
Bunch/Bundle	3	5	14
Field row crop, low & medium	3	5	7
Field row crop, tall	7	9	7
Ornamentals	6 to 7	8	12 hr. REI
Deciduous tree fruit	3 to 4	8	21
Tree nuts	18	greater than 30	45

Agricultural Postapplication Assessment

Crop Gouping	Days After Treatment Target MOE Achieved		PHI Days
	Short-term (target = 100)	Intermediate-term (target = 300)	
Root vegetables	2 to 3	4 to 5	14+
Curcurbit vegetables	3	5	7
Fruiting vegetables	2	3 to 4	1 to 5
Brassica vegetables	3 to 4	5 to 6	7
Leafy vegetables	2 to 3	4 to 5	10+
Vine & trellis crops	4 to 5	4 to 5	28

Occupational Postapplication Assessment

- Summary of Postapplication Risk
  - Forty crop/activity combinations assessed

		Day following treatment when MOE >target (i.e., meets the REI)						
		o	1st	2nd	3rd	4th	5th	>6th
Number of Scenarios (total 40)	Short-Term Target ~100	9	4	11	5	2	4	5
	Intermediate-Term ~300	4	1	3	6	10	5	11

Agricultural Postapplication Assessment

Uncertainties

- Lack of exposure data – spray drift, soil incorporated treatments
- Transfer Coefficients
- Extrapolating DFR from crop to crop
- Exposure Factors

Agricultural Incidents

California data (1982 – 1998)

- Rate of incidents in CA comparable to other insecticides
- 76 agricultural cases
- 499 non-agricultural cases
  - 75% occupational
- Occupational risk attributed to:
  - Hand application (38%)
  - Lack of PPE
  - Equipment failure
  - Inadequate precautions during maintenance

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Residential Exposure Assessment

Debbie Smegal
Health Effects Division
OPP

Residential Exposure Assessment

- Handler Exposure
  - Professionals (e.g., lawn care operators)
  - Homeowners/Residents
- Postapplication Exposure
  - Homeowners/Residents (e.g., children on treated lawns)

Residential Exposure Assessment (Professionals and Homeowners)

- Data Sources:
  - Registered labels
  - Use information
  - Chemical-specific studies
  - Pesticide Handlers Exposure Database (PHED)
  - Residential Standard Operating Procedures (SOPs)
  - ORETF studies

Residential SOPs

- Screening level methodology
- Updated assumptions based on Scientific Advisory Panel (SAP) comments
- Used to assess 2 of 6 homeowner handler scenarios
- Used to assess all 4 postapplication scenarios in conjunction with study data

Residential Exposure Assessment

- Four chemical-specific studies used to assess
  - 1 out of 8 PCO/LCO scenarios
  - 3 out of 6 homeowner handler scenarios
  - 3 out of 4 postapplication scenarios
  - 1 residential handler study
    - Passive dosimetry
    - biomonitoring

Handler Assessment Scenarios

Mixer/Loader	Applicator	Postapplication
■ Liquids ■ Granulars ■ Wettable powder	■ Push type spreader ■ Belly grinder ■ Sprinkler can ■ Low pressure handwand ■ Hose-end sprayer (HES) ■ Dust ■ Aerosol	■ Liquids ■ Granulars ■ Pet collars

Professional/Homeowner Handler Assessment

Scenarios Evaluated:

- Liquid Turf Treatment
  - Low pressure handwand
  - Conventional hose-end sprayer
  - Ready-to-use hose-end sprayer
  - Backpack sprayer
  - Handgun sprayer
- Granular Turf Treatment
  - Push-type spreader
  - Belly grinder
- Indoor Crack, Crevice and Spot Treatment (PCO only)
- Insecticidal dust application (PCO only)

Professional/Homeowner Handler Assessment

- Evaluated typical and maximum rates
- Dermal and inhalation exposure
- Short, intermediate and long-term (professional)
- Short-term (homeowner)

Professional Handler Results

- All professional handler risks exceed level of concern
  - All short-term Aggregate Risk Indices (ARIs) less than 1
  - All intermediate & long-term MOEs less than 300

Homeowner Handler Results

- Passive dosimetry:
  - All scenarios result in Aggregate Risk Indices (ARIs) less than 1 and are of concern
- Biomonitoring (0.5 acre) MOEs are less than 100 and are of concern for:
  - Ready-to-use hose-end sprayer
  - Conventional hose-end sprayer
- Biomonitoring (spot treatment, 4 gal.) MOEs greater than 100 for low pressure handwand and are not of concern

Homeowner Handler Results

- 0.5 acre Agency default lawn size
- 0.34 acre maximum lawn size assessed for granular products based on label restrictions
- 0.11 acre or 5000 ft^2
  - 1 quart treats 0.11 acre
  - Preliminary survey data suggests majority of people purchase 1 quart for lawn/ornamental use
  - Most biomonitoring results do not exceed level of concern
- Long pants should reduce risk

Biomonitoring Uncertainties

- Lack of dermal and inhalation pharmacokinetic data
- Possible incomplete urine collection
- Exposure compared to oral NOAEL
  - Oral NOAEL = 0.25 mg/kg/day
  - Inhalation LOAEL = 0.026 mg/kg/day
- May underestimate risks

Passive Dosimetry Uncertainties

- Compared inhalation exposures to 21-day inhalation endpoint based on whole body exposure
- Compared dermal exposure to 21-day dermal endpoint
- New toxicity data may impact risk

Postapplication Residential Assessment

Evaluated four major scenarios:

- Turf treatment
  - Liquid
  - Granular
- Indoor crack and crevice treatment
- Pet collar uses

Postapplication Residential Assessment

- Turf treatment exposure pathways
  - Dermal absorption (watered & non-watered)
  - Hand to mouth
  - Turf mouthing (object to mouth)
  - Soil ingestion
  - Granule ingestion
  - Inhalation (watered & non-watered)

Postapplication Residential Assessment

- Indoor crack & crevice
  - Inhalation
  - Dermal
- Pet collars
  - Dermal

Postapplication Residential Results

Turf Treatment

- Adults
  - Nearly all adult MOEs are not of concern except 0-2 hours inhalation exposures following liquid treatment (not watered-in)
- Children
  - Pathway specific MOEs exceed level of concern
    - Hand-to-mouth
    - Some inhalation MOES are of concern (mostly when product not watered-in)
    - Incidental granule ingestion

Postapplication Residential Results

Turf Treatment

- Children continued
  - AREIs exceed level of concern
  - Dermal and inhalation AREIs
    - Mostly a concern for liquid treatments
    - Generally not a concern for granular treatment
      - No air residues if watered-in
      - Chemical specific exposure study shows no air residues in 2 out of 3 locations (not watered-in)
      - Because 3rd location indicated air residues, assessment was conducted and could be of concern if not watered-in

Postapplication Residential Results

Indoor Uses

- Crack & crevice: inhalation & dermal
  - All MOEs exceed level of concern for children
  - Most MOEs exceed level of concern for adults
- Pet collars: dermal
  - All MOEs exceed level of concern for children
  - Some MOEs exceed level of concern for adults

Postapplication Residential Uncertainties

- Conservative exposure assumptions
  - 2 hour continuous contact with lawn
  - Contact with lawn immediately after treatment
    - ORETF survey indicates
      - 84% of people wait 2 hours before reentry
      - 66% of people wait 12 hours before reentry
  - 5% of application rate is transferred to child's wet hands based on EPA data
    - Registrant TTR data show 100 fold lower transfer to dry cotton cloths
  - Inhalation of air residues immediately after treatment (0-2 hours)

Postapplication Residential Uncertainties

- Used 21-day dermal and inhalation toxicity endpoints to assess 2 hour lawn exposure
  - New toxicity data may impact risk estimates
- Inhalation risks exclude vapor residues
- Air residues decline 2 to 10-fold within 8 hours
- TTR measurements were nondetectable within 2 days
- These assumptions are unlikely to underestimate risk

Residential Incidents

Poison Control Centers (PCC) data 1993 – 1996

- Nearly 12,000 suspected exposures
  - 55% adults
  - 36% children < 6 years old
- Most (86%) reported minor effects
  - e.g. headaches, nausea
- Rate of exposure incidents comparable to other insecticides
- Exposure to concentrates can lead to more severe effects than ready-to-use formulations

Aggregate Risk Assessment

- Aggregate risk assessment reflects mitigation measures
- Acute, short-term & chronic aggregate risk estimates (food & water) do not exceed level of concern
  - Exception: Surface water model estimates
- Mitigation measures should reduce water exposure

Diazinon

Ecological Risk and Water Resource Assessment

R. David Jones
James Felkel
Thomas Steeger
Dana S. Spatz

Environmental Fate and Effects Assessment

- Environmental Fate Assessment
  - Laboratory and Field Studies
- Water Resource Assessment
  - Modeling and Monitoring
- Ecotoxicity
  - Acute and chronic studies
  - Birds, mammals, insects, fish, aquatic invertebrates, and plants
- Ecological Risk Assessment
  - Exposure and Toxicity
  - Incidents

Environmental Fate and Water Resources

Non-agricultural uses of diazinon, including homeowner uses, have significantly affected both surface- and ground-water quality

Environmental Fate

- Diazinon is moderately persistent and mobile
  - Half-life in soil is approximately 6 weeks
  - 3-20 weeks in water by hydrolysis (depending on pH)
- Oxypyrimidine is more mobile and persistent than diazinon
- Diazoxon found in field studies, air, rain, fog and surface water

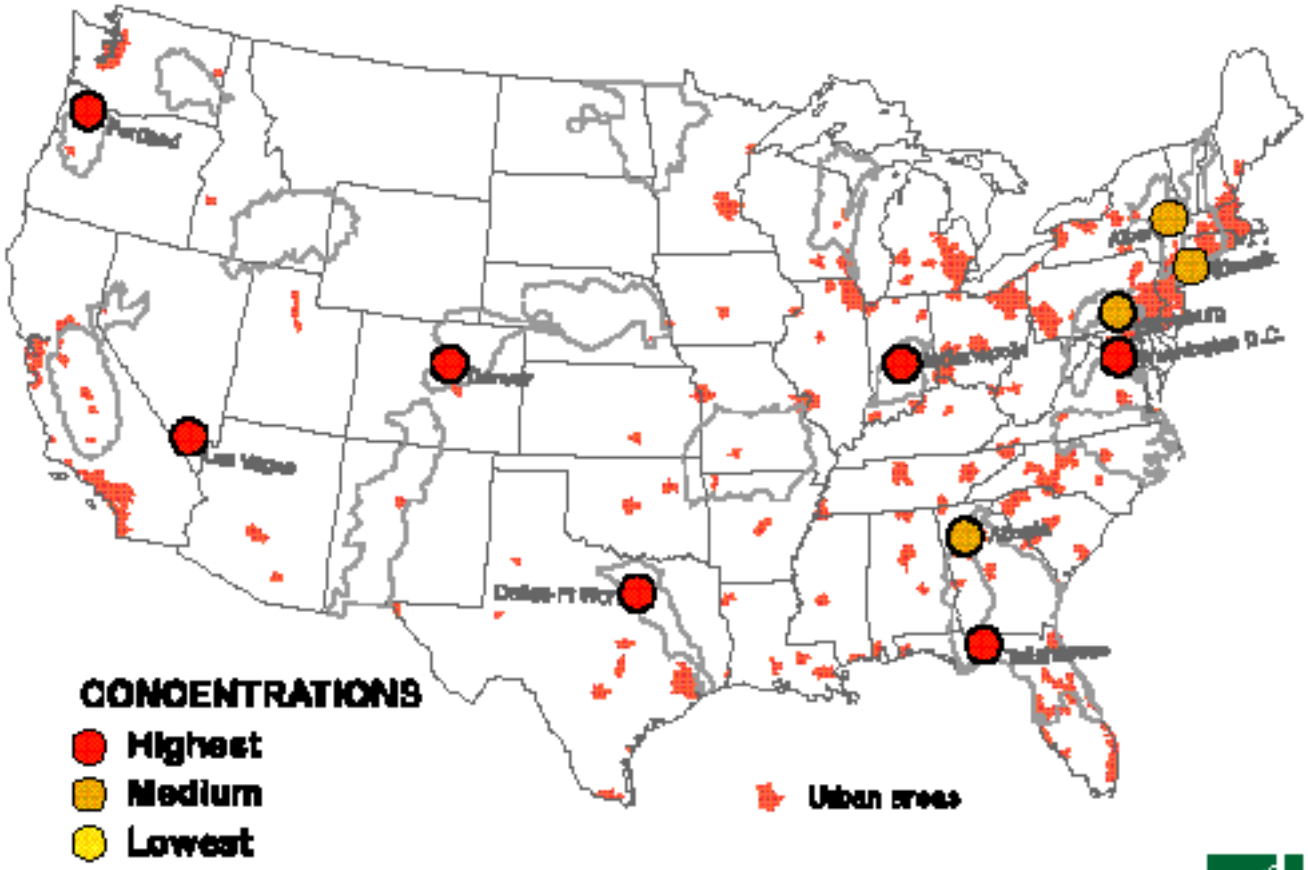
Diazoxon

- Ecotoxicity data indicate substantially greater toxicity for diazoxon than parent (100X - 10,000X)
- In lab study, diazoxon forms as a result of chlorination and ozonation of drinking water
- Diazoxon persists in treated water for at least 48 hours
  - More fate data needed

Environmental Occurrence

- According to USGS studies, diazinon is one of the most commonly found pesticides in air, rain, and fog
  - Highest concentration near major cities
- More common in urban areas
  - Associated with residential uses (ant control and lawn care) in California and Washington
  - Very high frequency of detections in targeted studies in urban areas

Insecticides were high in most urban streams and frequently exceeded guidelines for protecting aquatic life



USGS

Surface Water Monitoring

- Monitoring data indicate widespread occurrence of diazinon in surface water nationally
- Detected in the surface water of 24 states and the District of Columbia. Found in large rivers (Rio Grande, Mississippi, Columbia, and Colorado)
- Degradate impacts not well known

Dormant Spray

- Dormant spray use of diazinon on orchard crops has resulted in surface water contamination in California

Wastewater Treatment Facilities

- Diazinon occurs in discharge from wastewater treatment facilities
- Facilities in 14 states out of compliance with the Clean Water Act as a result of diazinon residues in effluent
- Permit Compliance System: 52% influent samples and 40% effluent samples contain diazinon

TMDL

- Waterways impaired under the TMDL program as a result of diazinon
- In California alone, 53 water bodies are impaired due to diazinon in urban runoff
- Eight TMDLs have been initiated in CA, including at least one in virtually every major uban area of the state

Drinking Water

- Found at drinking water intakes, but not in finished water, in 83 (of 245 total) samples from USGS Pilot Reservoir Monitoring Study
- 10 of 12 reservoirs had detections with frequencies of 7 to 96%
- Reported in wells in Missouri, Mississippi, and Virginia, and by USGS in 1.8% of nations major aquifers

Diazinon

Risks to Terrestrial Organisms

James Felkel

Environmental Fate & Effects Division

OPP

Ecological Risk Assessment: Toxicity and Exposure

- Risk Quotients (RQs), field studies, incidents
- Risk Quotients
  - Ratio of exposure concentration to toxicity endpoint (non-granular products)
  - Acute RQ = $\frac{\text{Peak Environmental Concentration}}{LC_{50} \text{ or } EC_{50}}$
  - Chronic RQ = $\frac{\text{Peak Environmental Conc.}}{\text{NOAEC}}$
- Ratio is compared to the Agency's Levels of Concern (LOC).

Risk to Birds

- Broadcast application of diazinon generally poses the greatest risk to birds of any registered pesticide on turf

Acute Toxicity- Birds

- Very high acute oral toxicity (mallard)
  - Lowest LD_{50} is approx. 1 mg/kg
  - Lowest LC_{50} is 32 ppm
- Just one granule or one treated seed is enough to kill a small bird

Chronic Toxicity - Birds

- Effects on avian reproduction began at about 16 ppm (8 ppm NOAEC)
- Both the avian reproduction effect levels and the avian LC_{50} are well below levels measured in the field
- Birds on turf will frequently encounter residue levels in the high 100 or low 200 ppm levels even with irrigation

Mammals

- Mammals are less sensitive than birds orally
- Diazinon is highly toxic to mammals dermally and very highly toxic based on inhalation exposure

Avian Risk

- Acute and chronic LOCs are exceeded for all uses (granular and liquid)
- Acute RQ values for birds were as high as 4,725; the level of concern is 0.5
- Field studies and incident reports support risk predicted by risk quotients

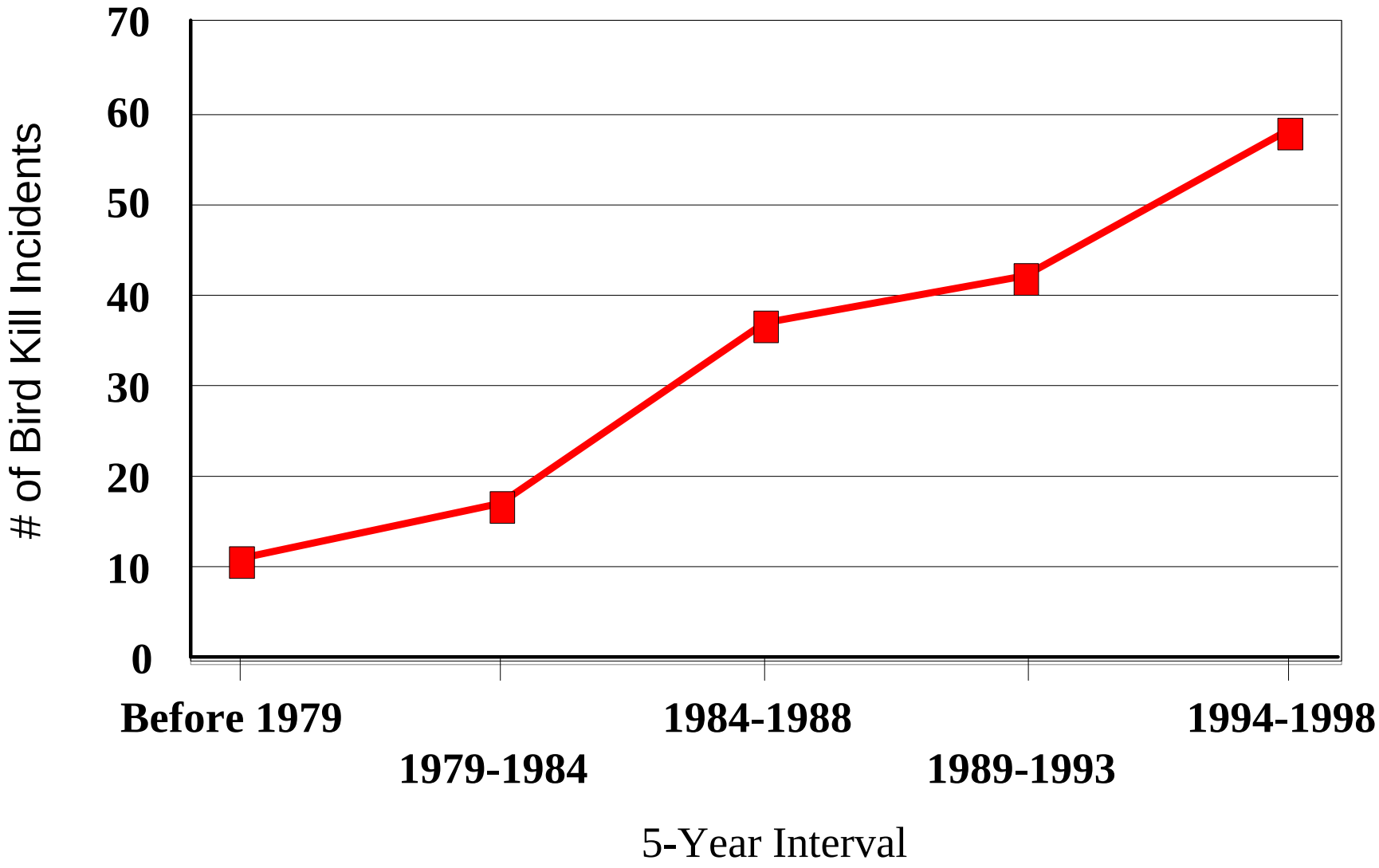
Incidents

- Second highest number of bird kills reported over all years
- Highest number of reported bird kill incidents of any pesticide in recent five year period (1994-1998)
- Where the treatment site for the incident is known, residential use has accounted for 52% of the reported cases

Incidents

- A large number of species have been killed, including ducks, geese, hawks, songbirds, woodpeckers, and others

Steady Trend of Increasing # of Bird Kills
Attributed to Diazinon in EIIS



Field Studies

- At a rate of 2 lbs ai/A (liquid formulation) on turf (well below maximum label rate), 85 ducks (American wigeon) were killed after feeding for just 30-40 minutes
  - Investigators scared birds away to prevent further mortality
- Large numbers of mortalities were also seen in studies on apples and corn

Diazinon

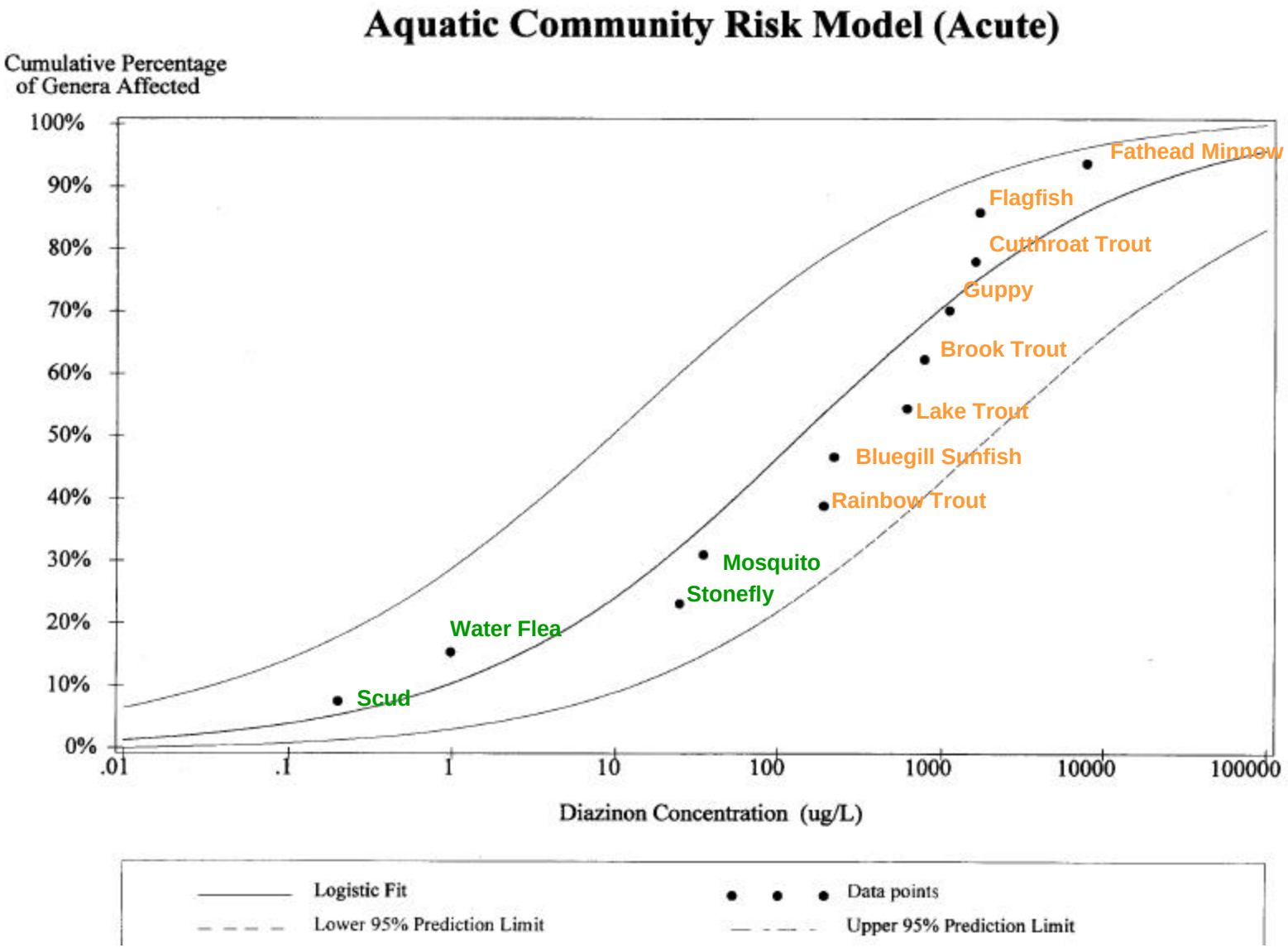
Risks to Aquatic Organisms

Thomas Steeger

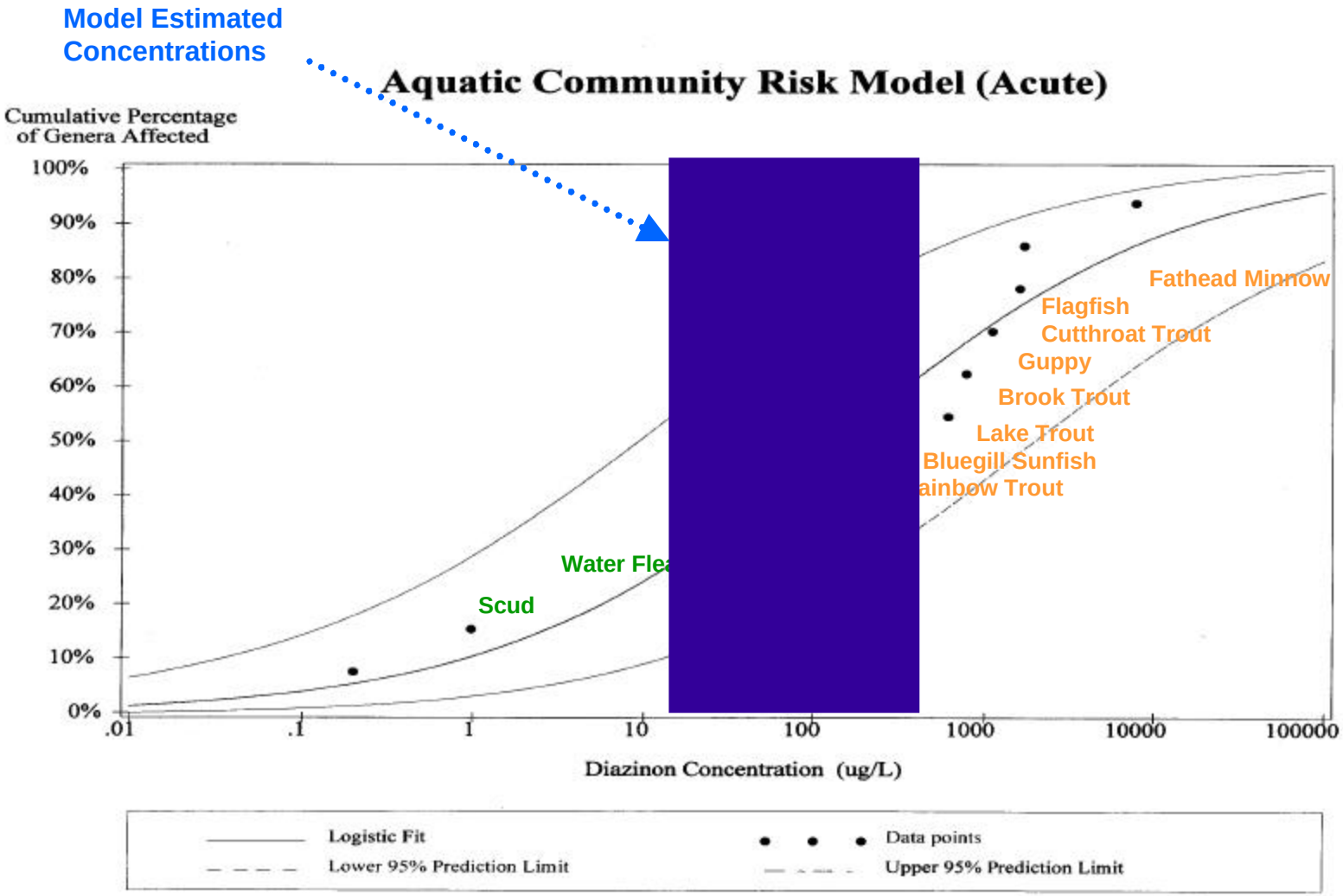
Environmental Fate & Effects Division

OPP

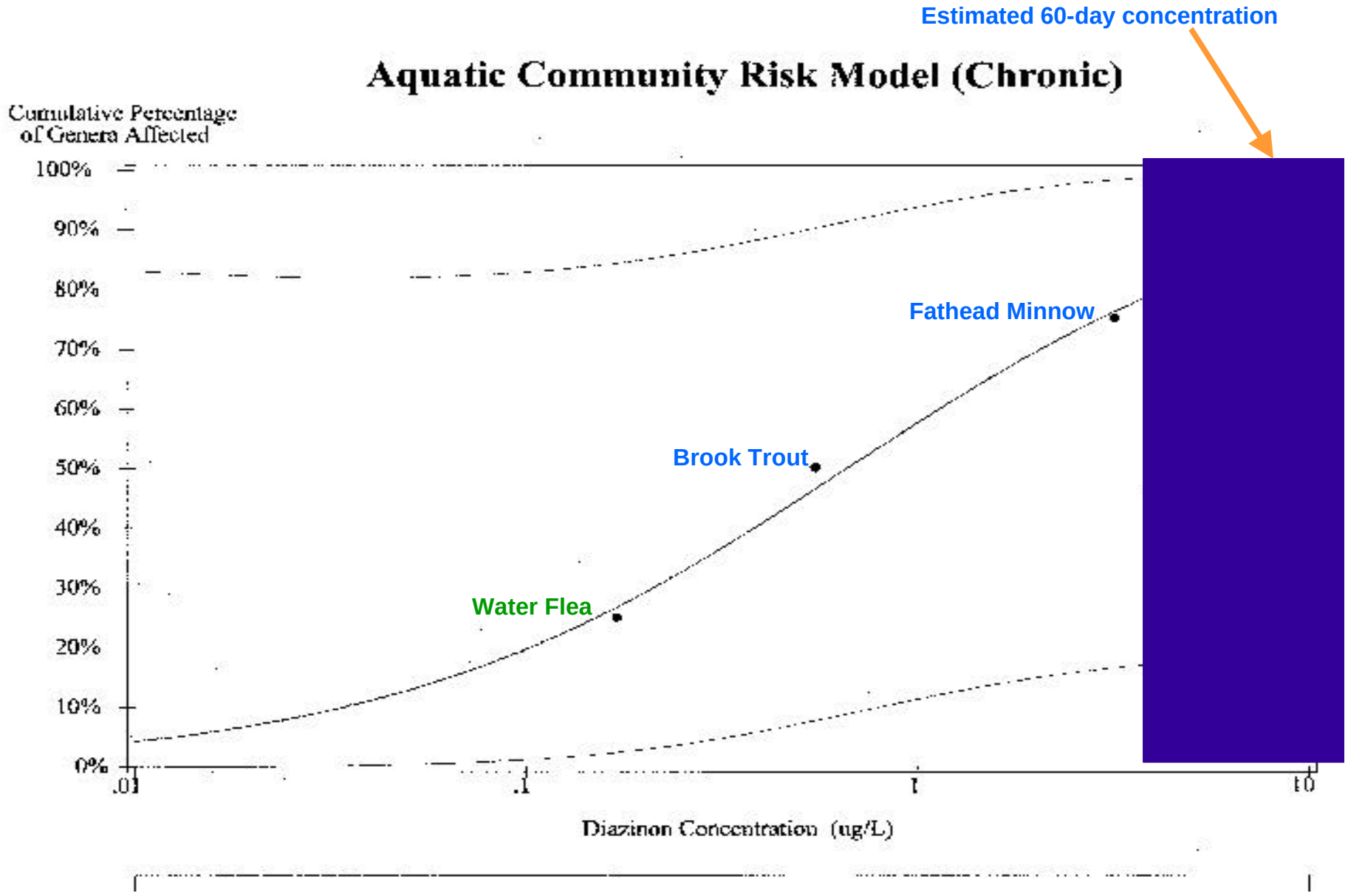
•**Diazinon is very highly toxic to freshwater fish and invertebrates following acute exposure; toxicity estimates spanned 5 orders of magnitude**



Based on estimated concentrations, RQ values for fish and invertebrates ranged from 0.1 – 2.0 and 44 – 2,145, respectively.

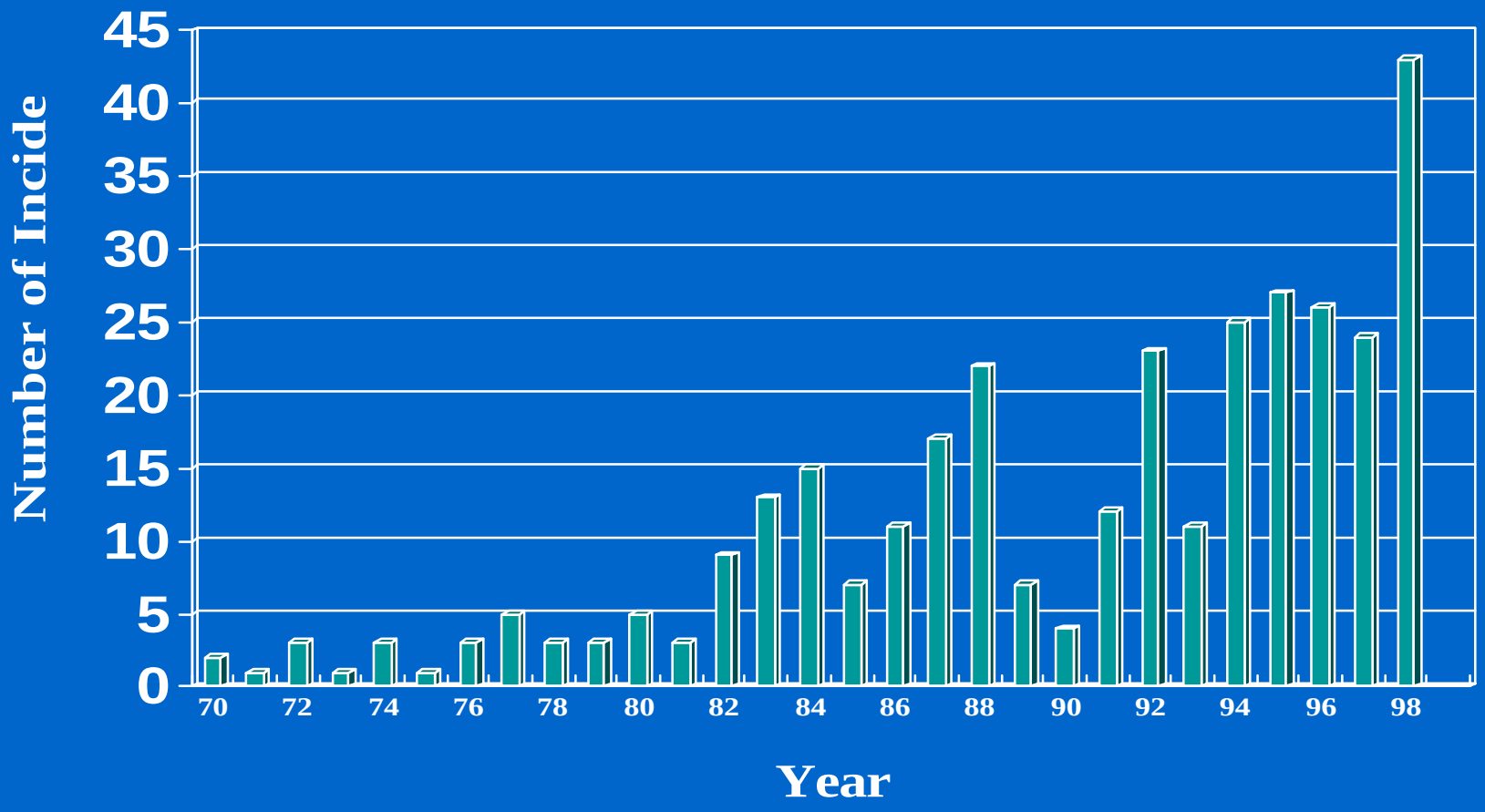


Chronic aquatic (freshwater) effect distribution spanned 3 orders of magnitude. Based on estimated concentrations, RQ values for fish and invertebrates ranged from 12 – 469 and 54 – 7,853, respectively.

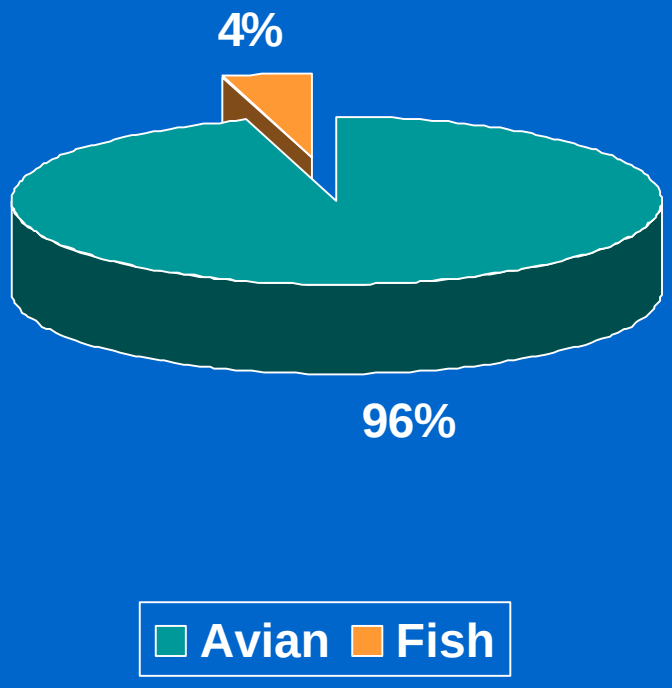


•Reported number of incidents showed a steady increase from 1970 through 1998.

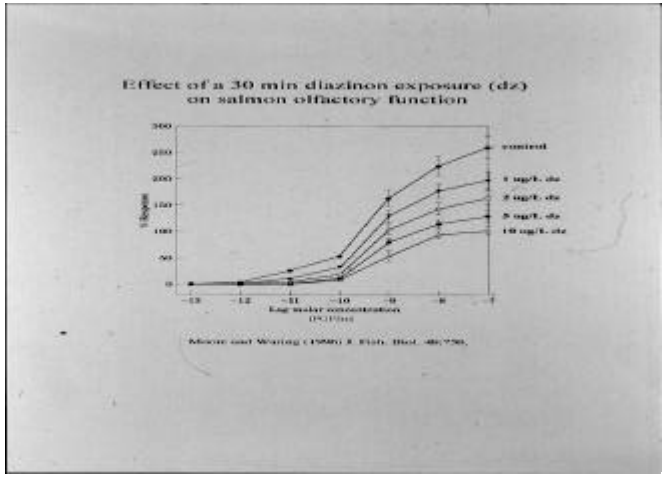
•It is unclear whether the increase number of incidents is a result of improved reporting.



- **Of the diazinon-related incidents, the majority (96%) involved birds while only 4% involved fish.**

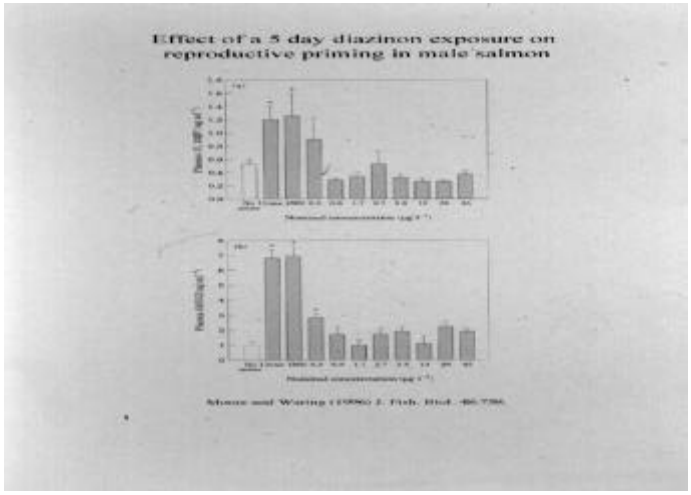


Endangered Species Effects

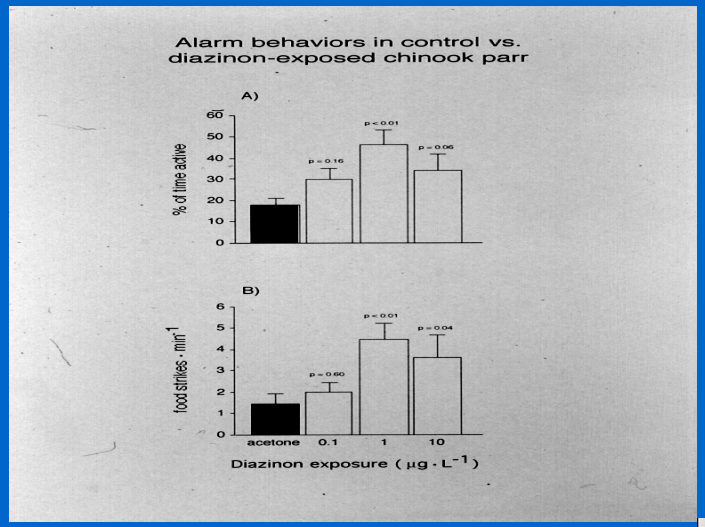


Recent literature (Moore and Waring 1996) indicates that at environmentally relevant concentrations, diazinon treatment resulted in diminished olfactory response (sense of smell) in Atlantic salmon

Diazinon exposure resulted in reduced responsiveness of male Atlantic salmon to female salmon pheromones.

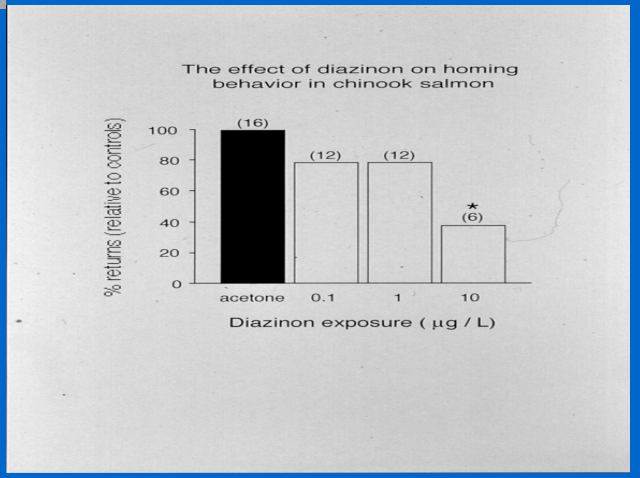


Endangered Species Effects



Recent literature (Scholz et al. 2000) demonstrated that exposure of Chinook salmon to diazinon diminished responsiveness to predatory events.

Chinook salmon exposed to diazinon exhibited reduced homing response.



DIAZINON

Endangered Species Considerations

Larry Turner
Field & External Affairs Division
OPP

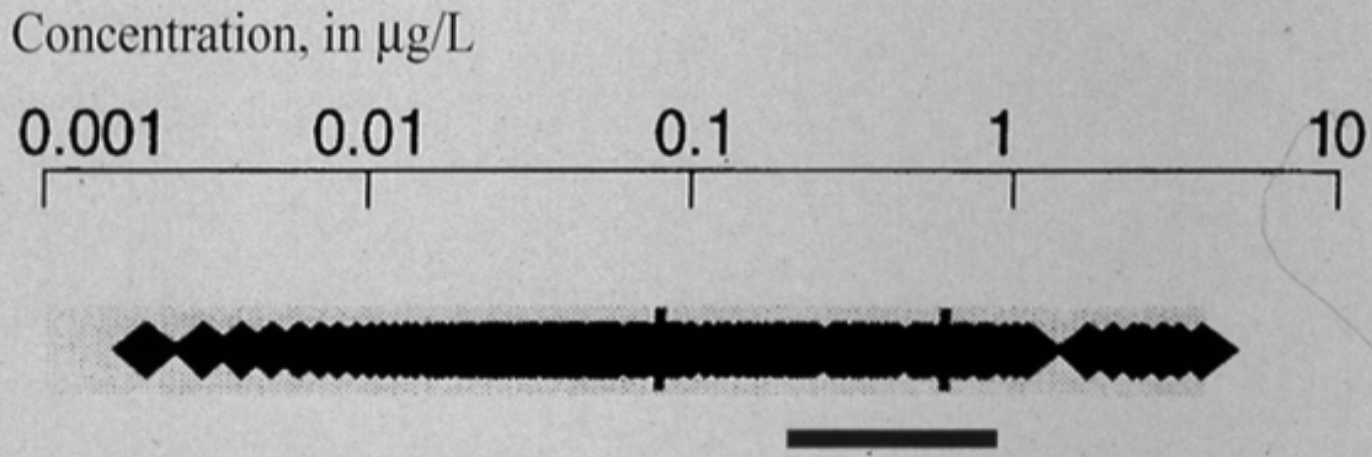
Endangered Species Act

- Section 7(a)(2)
  - "Each Federal agency shall, in consultation with and with the assistance of the Secretary, insure that any action authorized, funded, or carried out ... is not likely to jeopardize the continued existence of any endangered species or threatened species ... or result in the destruction or adverse modification of [critical] habitat..."
  - i.e., if a pesticide use "may affect" a listed species or critical habitat, OPP must consult with FWS or NMFS.

Endangered Species Act

- Section 3 (19)
  - "The term "take" means to harass, **harm**, pursue, hunt, shoot, wound, kill, trap, capture, or collect, or to attempt to engage in any such conduct."
- Sec. 9(a)(1)(D)
  - "[It is unlawful, with exceptions, to] take any such [threatened or endangered] species within the United States or the territorial sea of the United States."

Diazinon surface water detections in the San Joaquin basin (USGS NAWQA program)



- olfactory receptor function
- reproductive physiology
- antipredator behaviors

Source: USGS Circular 1159

Salmon and NAWQA residues for Diazinon

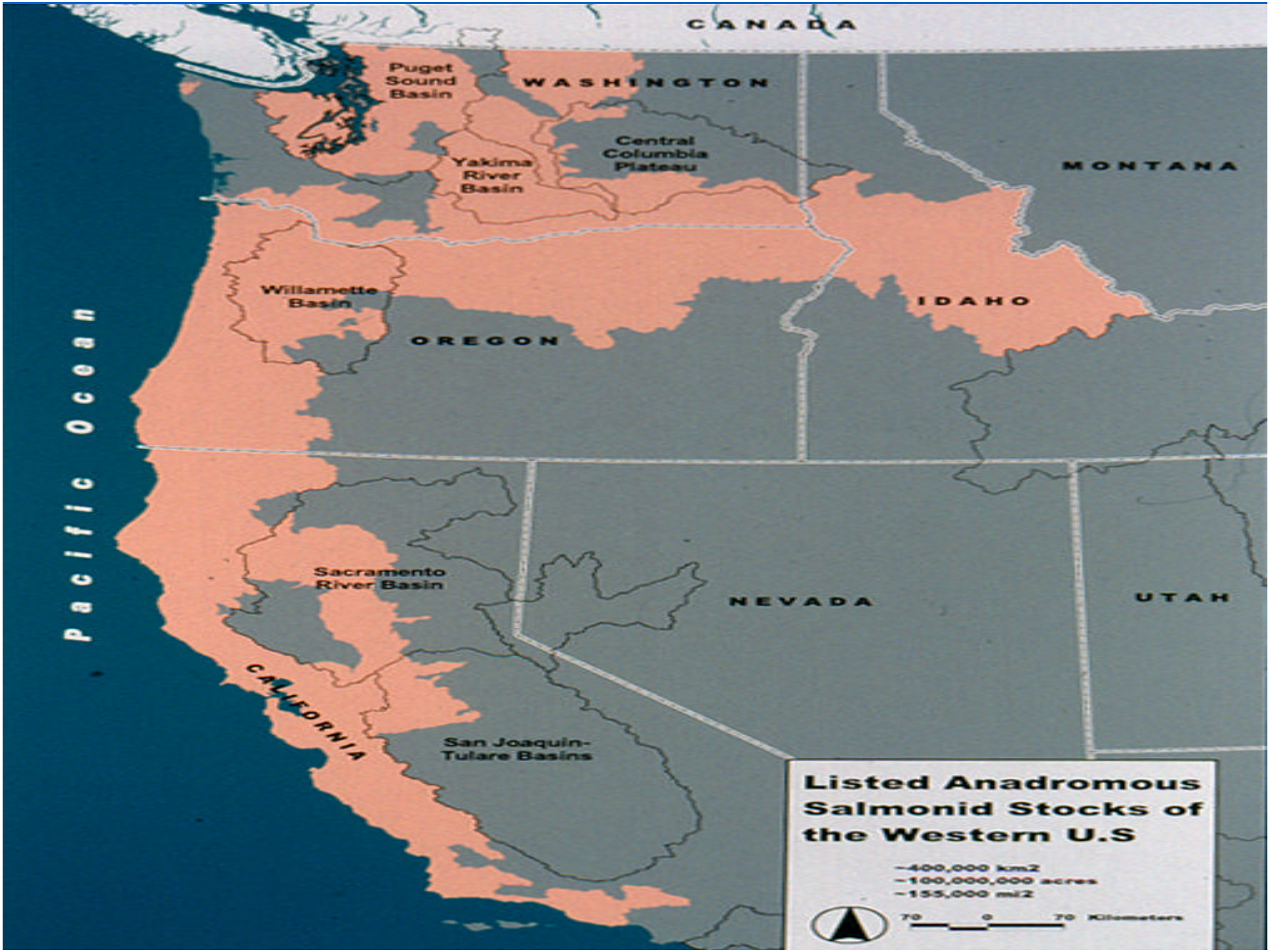
- Puget Sound (western Washington) Study Area
  - No agriculture
  - Diazinon detected in 100% of samples
    - Highest: 0.4 ppb
  - Exceeds USGS Aquatic Life chronic criteria
  - Exceeds NMFS salmon olfactory effect levels
  - Exceeds OPP endangered species acute criteria for invertebrate food supply

- Columbia Plateau (eastern Washington) Study Area
  - Almost all agriculture
  - Diazinon detected in 4% of samples
    - Highest: 0.052 ppb
  - Exceeds USGS Aquatic Life chronic criteria

Salmon and NAWQA residues for Diazinon

- Willamette (Oregon) Study Area
  - Mixed agriculture and non-agriculture
  - Diazinon detected in 35% of samples
    - Highest: 1.0 ppb
  - Exceeds USGS Aquatic Life chronic criteria
  - Exceeds NMFS salmon olfactory effect levels
  - Exceeds OPP endangered species acute criteria for invertebrate food supply

- San Joaquin-Tulare (California) Study Area
  - Mostly agriculture; some nonagriculture
  - Diazinon detected in 71% of samples
    - Highest: 5 ppb
  - Exceeds USGS Aquatic Life chronic criteria
  - Exceeds NMFS salmon olfactory effect levels
  - Exceeds OPP endangered species acute criteria for invertebrate food supply
  - Exceeds OPP endangered species acute criteria for fish lethality


CANADA
Puget Sound Basin
WASHINGTON
Central Columbia Plateau
Yakima River Basin
MONTANA
Willamette Basin
IDAHO
OREGON
Pacific Ocean
Sacramento River Basin
NEVADA
UTAH
CALIFORNIA
San Joaquin-Tulare Basins
Listed Anadromous Salmonid Stocks of the Western U.S
~400,000 km2
~100,000,000 acres
~155,000 mi2
70 0 70 Kilometers

Risk Summary and Next Steps

Mark Wilhite
Special Review and Reregistration Division
OPP

Indoor Non-Agricultural Risk Mitigation

All indoor non-agricultural uses to be removed

- Includes crack & crevice and pet collar use
- All retail sale must be completed by December 2002

Outdoor Non-agricultural Residential Risk Mitigation

All outdoor non-agricultural uses removed

- Reduce production at least 50% by 2003
- Stop formulation of end-use products June 2003
- All distribution and sale to retailers must be completed by August 2003
- Registrants buy back any unsold products as of December 2004

Agricultural Use Deletions

- Deletion of 26 uses/crops including alfalfa, cotton, peanuts, pecans, potatoes, sorghum, soybeans & sugarcane
- Revocation of tolerances for uses deleted

Effects of Mitigation

- Eliminates residential exposures and risks to children
- Removal of most outdoor use
  - Significantly reduces diazinon exposure from water
    - Especially in urban areas
- Reduces ecological exposure
- By 2003, total number of pounds of diazinon produced will be reduced by at least 75%

Summary of Risk

- Dietary risk not of concern based on food and water monitoring
  - Food risk is not of concern
  - Risk will be lower with cancellation of some agricultural uses
  - Water risk may be of concern based on surface water modeling

Summary of Risks

- Handler risk
  - Mixer/loader/applicator have risks of concern
- Postapplication risk
  - Most reentry intervals will be increased

Summary of Risks

- Ecological risk
  - Risks to birds, fish and mammals are high
  - Concern regarding the number of ecological incidents

Summary of Risks

- Environmental risk
  - Diazinon is one of the most commonly found pesticides in water, air, rain & fog
  - Diazinon's degradate diazoxon is found in surface water and may be formed as a result of drinking water treatment

Public Comment

- Public participation will allow comments
  - Focus on remaining issues – worker and ecological risk mitigation
  - 6f process for cancelled uses

Next Steps

- 60-day public comment period
- E-mail comments to:
  - opp-docket@epa.gov
- Mail comments to:

  U.S. EPA
  OP Pesticide Docket (7502C)
  401 M St. SW
  Washington, DC 20460

Contacts

- Benjamin Chambliss (703) 308-8174
- E-mail: chambliss.benjamin@epa.gov

Probabilistic Risk Assessment

- A probabilistic risk assessment was submitted based on an analysis of single species laboratory data and multispecies microcosm and mesocosm studies.
  - Although whole-effluent testing resulted in direct acute mortality to freshwater invertebrates, i.e., Ceriodaphnia, the analysis argues that these are unreasonable data on which to predict "ecological effects."
    - Laboratory toxicity tests confirm that EC50 values for invertebrates were below (0.2 – 0.98 ug/L) concentrations in effluent and that invertebrates would likely be affected.

Probabilistic Risk Assessment

- Exposure assessment underestimates acute risk potential since collection intervals were infrequent.
- Sampling sites do not represent most vulnerable exposure areas. Most sites were 3rd and 4th order rivers whereas 1st order streams, wetlands, and small impoundments would have the highest vulnerability to acute exposure.
- Serial nature of data fails to account for autocorrelation (serial correlation).
- PRA implies that organisms are exposed to a single pulse exposure; however, in reality, nontarget aquatic organisms are exposed to the entire range (chemograph) of concentrations.
- Differences in sampling techniques should have been better accounted for. Unfiltered samples likely overestimate exposure potential; however, since diazinon does not readily sorb to soils, it is less of an issue.
- No mention is made of diazoxon, the primary component of diazinon toxicity.

Probabilistic Risk Assessment

- Whether ecological functional equivalency is an acceptable alternative is a policy issue; however, the elimination of a complete taxon and its ultimate replacement by a more resistant species would represent a major change in the structure of a community.

- It is unlikely that a chemical would selectively remove a single taxon; rather, a distribution of effects would be more likely.

- Projecting the impacts to early fish life stages simply by assuming the effects were limited to cladocerans is simplistic and misleading. There is no mention of the vulnerability communities may experience due to decreased diversity or whether it is acceptable that communities can be impacted to the extent that entire taxa are likely to drop out. Also, if juvenile fish were able to successfully transition to alternate prey, could those prey sustain increased mortality given that **their** food source may have also been impacted, *i.e.*, relied on cladocerans to any extent?